

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

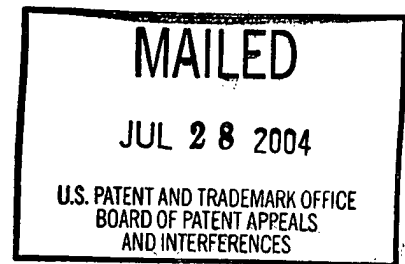
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LEO MARTIS and LEE W. HENDERSON

Appeal No. 2004-1260
Application No. 09/955,248

HEARD: June 24, 2004



Before SCHEINER, MILLS and GREEN Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-16, which are all of the claims pending in this application.

Claims 1 and 6 are illustrative of the claims on appeal and read as follows:

1. A peritoneal dialysis solution including bicarbonate at a level of less than or equal to 30 mM/L, having a carbon dioxide partial pressure that is less than 60 mmHg and including at least one weak acid at a level of between approximately 15 mEq/L and approximately 20 mEq/L selected from the group consisting of: lactate; pyruvate; citrate; isocitrate; cis-aconitase; α -ketoglutarate; succinate; fumarate; malate; and oxaloacetate.

6. A peritoneal dialysis solution comprising:

| | |
|---------------------------|---------------------------------|
| Dextrose (hydrous) (g/dl) | 1.5-4 |
| Sodium (mEq/L) | 100-140 |
| Chloride (mEq/L) | 70-110 |
| Calcium (mEq/L) | 0.0-4 |
| Magnesium (mEq/L) | 0.0-4 |
| Bicarbonate (mEq/L) | 20.0-30.0 |
| Weak acid (mEq/L) | 10.0-2 [sic 20.0] ¹ |

wherein the weak acid is at least one acid chosen from the group consisting of: lactate; pyruvate; citrate; isocitrate; cis-aconitase; α -ketoglutarate; succinate; fumarate; malate; and oxaloacetate, the solution having a carbon dioxide partial pressure that is less than 60 mmHg.

The references cited by the examiner are:

| | | |
|------------------|-----------|---------------|
| Veech (Veech I) | 4,663,166 | May 5, 1987 |
| Zander | 5,296,242 | Mar. 22, 1994 |
| Veech (Veech II) | 6,020,007 | Feb. 1, 2000 |

Schambye et. al. (Schambye), "The Cytotoxicity of Continuous Ambulatory Peritoneal Dialysis Solutions with Different Bicarbonate/Lactate Ratios," Peritoneal Dialysis International, Vol. 13, Supplement 2, pp. S116-S118 (1992)

Grounds of Rejection

Claims 1-2 and 4-8 stand rejected under 35 U.S.C. 102(b), as anticipated by Schambye in view of Zander.

Claims 1-2 and 4-8 stand rejected under 35 U.S.C. 102(b), as anticipated by Veech I in view of Zander.

¹ Appellants indicated during oral hearing that claims 6 and 11 included a typographical error and should read: Weak acid (mEq/L) 10.0-20.0. Appellants should make an appropriate amendment to the claims upon remand of the application.

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Claims 1-10 stand rejected under 35 U.S.C. 103(a), as obvious over Schambye in view of Zander.

Claims 1-16 stand rejected under 35 U.S.C. 103(a), as obvious over Veech I in view of Zander.

Claims 1-16 stand rejected under 35 U.S.C. 103(a), as obvious over Veech II in view of Zander.

The rejection of claims 1-16 under 35 U.S.C. 103(a), as obvious over Veech II in view of Zander is reversed. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(b), as anticipated by Veech I in view of Zander is reversed. The rejection of claims 1-5 under 35 U.S.C. 103(a), as obvious over Veech 1 in view of Zander is reversed.

The application is remanded to the examiner for further consideration of the following consistent with the discussion above: the rejection of claims 1-2 and 4-8 under 35 U.S.C. 102(b), as anticipated by Schambye in view of Zander, the rejection of claims 1-10 under 35 U.S.C. 103(a), as anticipated by Schambye in view of Zander; the rejection of claims 6-8 under 35 U.S.C. 102(b), as anticipated by Veech 1 in view of Zander; the rejection of claims 6-16 under 35 U.S.C. 103(a), as obvious over Veech 1 in view of Zander.

DISCUSSION

Background

The present invention relates to a peritoneal dialysis composition having specific ingredients. Prior peritoneal dialysis solutions, when used on patients who are deficient in lactate metabolism and/or who also experience or suffer from hepatic failure or shock, can cause lactic acidosis. This syndrome includes characteristic symptoms of hyperventilation, abdominal pain, and disturbances in consciousness when the patient receives lactate-containing peritoneal dialysis fluids. Specification, page 2.

In order to address this issue, peritoneal dialysis solutions in which lactate is completely replaced by bicarbonate have been proposed. However, in order to balance total body hydrogen ion content against metabolically generated hydrogen, and to maintain normal plasma carbonic acid and bicarbonate concentrations, it is necessary to use bicarbonate concentrations that are considerably in excess of normal.

Specification, page 3.

The compositions of the invention include a weak acid with a pKa of less than 5. These weak acids are chosen so as to be normal biochemical intermediates of glucose metabolism. The weak acid is present in an amount that would offset the daily metabolic hydrogen production of approximately 1 mEq/Kg/day. Specification, page 7.

35 U.S.C. § 103(a)

Claims 1-16 stand rejected under 35 U.S.C. § 103(a), as obvious over Veech II in view of Zander.

The examiner argues that “Veech [II] teaches a solution, which can be used to correct acidosis, for dialysis and/or fluid, electrolyte or nutrient replacement. ... In particular the type C solutions are suitable for use in peritoneal dialysis. ... The broadest range amount of each component is given in Table II. However, Veech [II] teaches that to be physiologically advantageous it is generally preferred to maintain levels of the components at values, which are approximately physiologic (see column 5, lines [sic] 65 to column 6, lin 13.) The most preferred pH of the solution is about 7.4. ...” Answer, page 8.

The examiner acknowledges that Veech II “does not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.” Id.

Zander is relied on by the examiner for the disclosure that “dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO₂ partial pressure correspond to the physiological blood plasma values...” Answer, pages 5-6. Zander discloses that it is the bicarbonate and weak acid that determine CO₂ partial pressure (see Zander at column 3, lines 11-16, wherein it is taught that the reaction between the bicarbonate and metabolizable organic acids produces the CO₂ partial pressure). Answer, pages 3-4.

The examiner concludes (Answer, page 9):

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Veech in such a way as to obtain a $p\text{CO}_2$ that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

Appellants argue, "[w]ith respect to Veech II, the Patent Office principally relies on its teachings regarding a Type C solution that is allegedly suitable for use in peritoneal dialysis. See, Examiner's Answer, page 8. The bicarbonate and weak acid concentrations of the Type C solution can broadly range from 0-40 mMole/L and 0-55 mMole/L, respectively, as disclosed in Veech II at Table II." Reply Brief, page 5.

Indeed, at bicarbonate concentrations that are considerably in excess of normal as disclosed in the Veech [II] reference, a partial pressure of carbon dioxide that is at least twice the physiologic partial pressure of carbon dioxide (e.g., greater than 80 mmHg) is required in order to maintain the peritoneal solution at a physiological pH.

Id.

We agree with appellants that the examiner has failed to present a prima facie case of obviousness over Veech II in view of Zander. Appellants argue that only a narrow range of weak acid concentrations will maintain an appropriate physiological pH and carbon dioxide partial pressure. Reply Brief, pages 5-6. We do not find that the examiner has provided sufficient evidence to support the position that the entire range of weak acid disclosed in Veech II provides the appropriate physiological pH and carbon dioxide partial pressure, or sufficient evidence that one of ordinary skill in the art would have been led to the narrow range of weak acid within the broad range disclosed

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in Veech II to arrive at the claimed carbon dioxide partial pressure.

In In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), a predecessor of our appellate reviewing court set out the rule that the discovery of an optimum value of a variable in a known process is normally obvious. Exceptions to this rule have been found in cases where the results of optimizing a variable, which was known to be result effective, were unexpectedly good. In re Waymouth, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974). Another exception is the case in which the parameter optimized was not recognized to be a result-effective variable. See In re Antonie, 559 F.2d 618, 619, 195 USPQ 6, 8 (CCPA 1977). It was determined in In re Sebek, 465 F.2d 904, 907, 175 USPQ 93, 95 (CCPA 1972) that in "an area of technology shown to be highly unpredictable in process values, the discovery of optimum values not in any way suggested by the prior art is more likely to be unobvious than obvious within the meaning of § 103."

Appellants have presented argument that the narrow range of weak acid within the broad ranges (not previously recognized as a result effective variable in the art) disclosed in Veech II results in a carbon dioxide partial pressure which is physiological. In our view, the examiner has not presented sufficient evidence that one of ordinary skill in the art would have been led to the narrow range of weak acid within the broad range disclosed in Veech II to arrive at the claimed carbon dioxide partial pressure.

The rejection of the claims for obviousness over Veech II in view of Zander is reversed.

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35 U.S.C. § 102(b) and § 103(a)

Claims 1-2 and 4-8 stand rejected under 35 U.S.C. 102(b), as anticipated by Veech I in view of Zander. Claims 1-16 stand rejected under 35 U.S.C. § 103(a), as obvious over Veech I in view of Zander.

It is the examiner's position that (Answer, page 4):

Veech [I] discloses preferred peritoneal dialysis solutions comprising osmotically active substances such as glucose (dextrose 83-237 mmole/L), sodium (130 to 145 mmole/L), chloride (93-102 mmole/l), calcium (1 to 1.5 mmole/L), magnesium (0.3 to 1 mmole/L), bicarbonate (25 to 30 mmole/L), lactate/plus pyruvate (2 to 12) and carbon dioxide (0 to 2 mmole/L), see column 41, table VIII and column 37, line 41.

Veech [I] discloses a peritoneal dialysis solution which has the claimed bicarbonate and weak acid concentrations. Therefore, the peritoneal dialysis solution of Veech inherently exhibits the claimed CO₂ partial pressure since it is the bicarbonate and weak acid that determine the CO₂ partial pressure (see Zander at column 3, lines 11-16...)

The examiner argues that the burden shifts to appellants to prove that the dialysis solution of Veech I does not necessarily or inherently possess the characteristics of the claimed peritoneal dialysis solution. Answer, pages 4-5.

With respect to Veech I, appellants argue that (Reply Brief, pages 5-6)

Veech I discloses peritoneal dialysis solutions with bicarbonate and weak acid concentrations that broadly range from 0 mmole/L to 60 mmole/L. Veech I even discloses preferred peritoneal dialysis solutions that broadly range in bicarbonate concentration from 25 mmole/L to 45 mmole/L and weak acid concentration from 2 mmole/L to 10 mmole/L. See Veech I, Table VI.

Appellants argue that Veech does not address the issue of metabolic acidosis and that (Reply Brief, page 5):

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Indeed, at bicarbonate concentrations that are considerably in excess of normal as disclosed in the Veech references, a partial pressure of carbon dioxide that is at least twice physiologic partial pressure of carbon dioxide (e.g., greater than 80 mmHg) is required in order to maintain the peritoneal dialysis solutions at a physiological pH.

With respect to claim 1, appellants argue that the preferred weak acid concentration disclosed in Veech I is different than the weak acid concentration required by the claim, of from between 15mEq/L to 20 mEq/L. Reply Brief, page 3. We agree with appellants, that with respect to claim 1, the examiner has failed to present evidence of anticipation of the claimed weak acid concentration. The most relevant example of Veech I is the preferred weak acid values set forth in Table VIII of 2-12 mEq/L. The examiner has not provided claim interpretation or analysis indicating that the language "approximately 15 mEq/L and approximately 20 mEq/L" of weak acid would have been understood by those of ordinary skill in the art to include 12 mEq/L. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(b), as anticipated by Veech I in view of Zander is reversed. The rejection of claims 1-5 under 35 U.S.C. 103(a), as obvious over Veech I in view of Zander is reversed.

REMAND

Our consideration of the record leads us to conclude that other issues in this case are not in condition for a decision on appeal. Accordingly, we remand the application to the examiner to consider the following issues and take appropriate action.

Veech I

In claim 6 of the present application, the weak acid concentration is not the same as that of claim 1 (15mEq/L to 20 mEq/L), but is from 10mEq/L to 20 mEq/L. It would appear, as indicated by the examiner in the Answer, that the preferred components of the peritoneal dialysis solution identified in Table VIII of Veech I (Column 41, lines 20-45), are substantially the same as the peritoneal dialysis solution of claim 6.

For the examiner's part, upon remand of the application, the examiner should determine if enough data is present in the preferred values of the peritoneal dialysis solution set forth in Table VIII of Veech I to determine the carbon dioxide partial pressure of the peritoneal dialysis solution of Veech I using the Henderson-Hasselbach equation.

If the examiner should determine that not enough data is available in Veech I to determine the carbon dioxide partial pressure of the peritoneal dialysis solution described therein, the examiner should then shift the burden of proof under the principles of In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) to appellants to determine the carbon dioxide partial pressure.²

² Table VIII indicates that total non-ionics in the peritoneal dialysis solution are between 84 and 238 mM/L. Non-ionics are indicated by Veech I at column 18, lines 38-42 to include glucose, glycerol, fructose, sorbitol and the like. Dextrose is D-glucose.

Under the principles of In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977), a patent owner's burden under the circumstances presented herein was described as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

The application is remanded to the examiner for such an analysis.

Schambye

Schambye, also stands on a different footing than Veech II. We remand the application to the examiner, and encourage appellants and the examiner to work closely together to determine whether example 9c of Schambye meets the limitations of claim 1. It would reasonably appear that the pyruvate and lactate (weak acid) values when combined in example 9c of Schambye are equivalent to the 15 m/Eq, as claimed.

Moreover, the examiner should determine if enough data is present in example 9c of Schambye to determine the carbon dioxide partial pressure using the Henderson-Hasselbach equation.

If the examiner should determine that not enough data is available in Schambye

If the examiner should determine that not enough data is available in Schambye example 9c to determine the carbon dioxide partial pressure of the peritoneal dialysis solution described therein, the examiner should then shift the burden of proof under the principles of In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) to show that the dialysis solution in Schambye does not possess the claimed carbon dioxide partial pressure. It would reasonably appear that appellants could determine the pKa of the peritoneal dialysis solution of Schambye example 9c to obtain a carbon dioxide partial pressure for the solution disclosed therein, as was done for the prior art peritoneal dialysis solution provided in the Declaration of Leo Martis of record. If appellants cannot readily determine the carbon dioxide partial pressure of solution 9c of Schambye, either from the data presented in Schambye or by determination of the pKa through experimentation, the appellants should specifically state for the record why it is impossible to determine the carbon dioxide partial pressure of solution 9c of Schambye.

We are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

CONCLUSION

The rejection of claims 1-16 under 35 U.S.C. 103(a), as obvious over Veech II in view of Zander is reversed. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(b), as anticipated by Veech I in view of Zander is reversed. The rejection of claims 1-5 under 35 U.S.C. 103(a), as obvious over Veech 1 in view of Zander is reversed.

The application is remanded to the examiner for further consideration of the following consistent with the discussion above: the rejection of claims 1-2 and 4-8 under 35 U.S.C. 102(b), as anticipated by Schambye in view of Zander, the rejection of claims 1-10 under 35 U.S.C. 103(a), as anticipated by Schambye in view of Zander; the rejection of claims 6-8 under 35 U.S.C. 102(b), as anticipated by Veech 1 in view of Zander; the rejection of claims 6-16 under 35 U.S.C. 103(a), as obvious over Veech 1 in view of Zander.

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This application, by virtue of its "special" status, requires an immediate action.
MPEP § 708.01(D) (8th ed., rev. 1, February 2003). It is important that the Board be
informed promptly of any action affecting the appeal in this case.

REVERSED-IN-PART AND REMANDED



TONI R. SCHEINER
Administrative Patent Judge



DEMETRA J. MILLS
Administrative Patent Judge



LORA M. GREEN
Administrative Patent Judge

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